

**In the Claims:**

✓ Please delete claims 1-19 without prejudice or disclaimer of the subject matter contained therein.

Please add the following new claims.

--20. A recombinant nucleic acid construct comprising at least one regulatory nucleic acid that is operatively linked to a nucleic acid sequence to be expressed, wherein said at least one regulatory nucleic acid sequence comprises the regulatory elements:

HF 1a and 1b consisting of nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides 2207 to 2219 of SEQ ID NO: 1;

or a functional homolog of said regulatory elements.

*B* 21. The construct of claim 20 that is effective to obtain heart- or heart cavity-specific expression of said nucleic acid to be expressed and does not compromise a CSS regulatory element consisting of nucleotides 682 to 724 of SEQ ID NO: 1.

22. The nucleic acid construct according to claim 20, wherein said regulatory nucleic acid sequence is obtained from a mammalian genome.

23. The nucleic acid construct according to claim 20, wherein said regulatory nucleic acid sequence is obtained from a human or rodent genome.

24. The nucleic acid construct according to claim 22, wherein said regulatory nucleic acid sequence is obtained from a rat genome.

25. The nucleic acid construct according to claim 20, wherein said regulatory nucleic acid sequence comprises a nucleic acid selected from the group consisting of

from approximately +18 to approximately -800;  
from approximately +18 to approximately -1600;  
from approximately +18 to approximately -1800;  
from approximately +18 to approximately -2100;  
from approximately +18 to approximately -2700;  
from approximately -19 to approximately -800  
from approximately -19 to approximately -1600;  
from approximately -19 to approximately -1800;  
from approximately -19 to approximately -2100; and  
from approximately -19 to approximately -2700;

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each with respect to the transcription starting point of the myosin light chain 2 gene.

26. The nucleic acid construct according to claim 20, wherein said regulatory nucleic acid sequence also comprises an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1 and/or the HF 2 element consisting of nucleotides 2271 to 2289 of SEQ ID NO 1; or a functional homolog of said E box or HF 1 elements.

27. The nucleic acid construct according to claim 20, wherein said regulatory nucleic acid sequence also comprises a CSS element consisting of nucleotides 682 to 724 of SEQ ID NO: 1; or a functional homolog of said CSS element.

28. The nucleic acid construct according to claim 20, wherein said construct is DNA or RNA.

29. The nucleic acid construct according to claim 28, further comprising a virus vector and wherein said construct is optionally complexed with liposomes.

30. The nucleic acid construct according to claim 29, wherein said virus vector is an adenovirus vector or adeno-associated virus vector.

31. The nucleic acid construct according to claim 30, wherein said adenovirus vector is a replication deficient adenovirus vector.

32. The nucleic acid construct according to claim 31, wherein said replication deficient adeno-associated virus vector consists of two inverted terminal repetition sequences.

33. The nucleic acid construct according to claim 20, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

34. The nucleic acid construct of claim 33, wherein said proteinaceous gene product is selected from a dystrophin, a  $\beta$  adrenergic receptor, or a nitric oxide synthetase.

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35. The nucleic acid construct according to claim 20, wherein the nucleic acid sequence to be expressed encodes an antisense nucleic acid or a ribozyme.

36. The nucleic acid construct according to claim 33 wherein the nucleic acid to be expressed further comprises one or more non-encoding sequences and/or one polyadenylation signal sequence.

37. The nucleic acid construct according to claim 34 wherein the nucleic acid to be expressed further comprises one or more non-encoding sequences and/or one polyadenylation signal sequence.

38. A process for making a composition for heart-specific expression of a desired nucleic acid to be expressed comprising making a construct by operatively linking at least one regulatory nucleic acid sequence comprising

HF 1a and 1b consisting of nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides 2229 to 2241 of SEQ ID NOA; and

HF 3 consisting of nucleotides 2207 to 2219 of SEQ ID NO: 1;

to said nucleic acid to be expressed that encodes a proteinaceous gene product, an antisense nucleic acid, or a ribozyme.

*B. ant.* 39. The process according to claim 38, further comprising cloning said construct in a virus vector and optionally complexing the product with liposomes.

40. A method for delivering a desired nucleic acid to cardiac muscle cells comprising administering a nucleic acid construct according to claim 20, optionally contained in a virus vector and

further optionally complexed with liposomes, to cardiac tissue of a subject.

41. The method of claim 40 wherein the subject suffers from a heart disease.

42. The method of claim 41, wherein said heart disease is a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

*sub 12*  
43. A pharmaceutical composition comprising a nucleic acid construct according to claim 20 and a pharmaceutically acceptable carrier.

*B1 Cont*  
44. The pharmaceutical composition of claim 42, that expresses said nucleic acid to be expressed specifically in the heart or the heart cavity of a subject to which said composition is administered.

45. A heart tissue-specific regulatory nucleic acid sequence comprising the regulatory elements:

HF 1a and 1b consisting of nucleotides 2340 to 2361 of SEQ ID NO: 1;

MLE1 consisting of nucleotides 2229 to 2241 of SEQ ID NO 1; and  
HF 3 consisting of nucleotides 2207 to 2219 of SEQ ID NO: 1;  
or a functional homolog of said regulatory elements.

46. The regulatory sequence of claim 45, wherein said regulatory acid sequence is obtained from a mammalian genome.

47. The regulatory sequence according to claim 46, wherein said regulatory nucleic acid sequence is obtained from a human or rodent genome.

48. The regulatory sequence according to claim 46, wherein said regulatory nucleic acid sequence is obtained from a rat genome.

49. The regulatory sequence according to claim 46, wherein said sequence comprises the nucleic acids selected from the group consisting of

from approximately +18 to approximately -800;  
from approximately +18 to approximately -1600;  
from approximately +18 to approximately -1800;  
from approximately +18 to approximately -2100;

from approximately +18 to approximately -2700;  
from approximately -19 to approximately -800;  
from approximately -19 to approximately -1600;  
from approximately -19 to approximately -1800;  
from approximately -19 to approximately -2100; and  
from approximately -19 to approximately -2700;

each with respect to the transcription starting point of the myosin light chain 2 gene.

50. The regulatory sequence according to claim 45, further comprising an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1 and/or an HF 2 element consisting of nucleotides 2271 to 2289 of SEQ ID NO: 1; or a functional homolog of said E box or HF 1 elements.

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Cont. 51. The nucleic acid construct according to claim 46, further comprising a CSS element consisting of nucleotides 682 to 724 of SEQ ID NO: 1; or a functional homolog of said CSS element.

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C1 52. A recombinant virus vector comprising a virus vector, a nucleic acid construct comprising at least one regulatory nucleic acid sequence of the 5' end of a myosin light chain 2 gene that is operatively linked to a nucleic acid sequence to be expressed,



wherein said recombinant virus vector is optionally complexed with liposomes.

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53. The recombinant virus vector of claim 52, wherein said at least one regulatory nucleic acid sequence comprises the regulatory elements:

HF 1a and 1b consisting of nucleotides 2340 to 2361 of SEQ ID NO: 1;

MLE1 consisting of nucleotides 2229 to 2241 of SEQ ID NO: 1; and  
HF 3 consisting of nucleotides 2207 to 2219 of SEQ ID NO: 1;  
or a functional homolog of said regulatory elements.

54. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence is obtained from a mammalian genome.

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55. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence is obtained from a human or rodent genome.

56. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence is obtained from a rat genome.

57. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence comprises the nucleic acids of positions

from approximately +18 to approximately -800;  
from approximately +18 to approximately -1600;  
from approximately +18 to approximately -1800;  
from approximately +18 to approximately -2100;  
from approximately +18 to approximately -2700;  
from approximately -19 to approximately -800;  
from approximately -19 to approximately -1600;  
from approximately -19 to approximately -1800;  
from approximately -19 to approximately -2100; and  
from approximately -19 to approximately -2700;

each with respect to the transcription starting point of a myosin light chain 2 gene.

58. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence also comprises an E box element consisting of nucleotides 2328 to 2383 of SEQ ID NO: 1 and/or an HF 2 element consisting of nucleotides 2271 to 2289 of SEQ ID NO: 1; or a functional homolog of said E box or HF 1 elements.

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59. The recombinant virus vector according to claim 52, wherein said regulatory nucleic acid sequence also comprises a CSS sequence element consisting of nucleotides 682 to 724 of SEQ ID NO: 1; or a functional homolog of said CSS element.

60. The recombinant virus vector according to claim 52, wherein the construct is a DNA or RNA sequence.

61. The recombinant virus vector according to claim 60, wherein said virus vector is an adenovirus vector or an adeno-associated virus vector.

62. The recombinant virus vector according to claim 60, wherein said virus vector is a replication deficient adenovirus vector.

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63. The recombinant virus vector according to claim 62, wherein said replication deficient adeno-associated virus vector consists of two inverted terminal repetition sequences (ITR).

64. The recombinant virus vector according to claim 52, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

65. The recombinant virus vector according to claim 64, wherein the proteinaceous gene product is selected from a dystrophin, a  $\beta$  adrenergic receptor or a nitric oxide synthetase.

66. The recombinant virus vector according to claim 52, wherein the nucleic acid sequence to be expressed encodes an antisense nucleic acid or a ribozyme.

67. The recombinant virus vector of claim 64, wherein the nucleic acid to be expressed further comprises one or more non-coding sequences and/or a polyadenylation signal sequence.

68. The recombinant virus vector of claim 66, wherein the nucleic acid to be expressed further comprises one or more non-coding sequences and/or a polyadenylation signal sequence.

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69. A method for delivery of a desired gene to cardiac muscle cells, which method comprises administering a recombinant virus vector according to claim 52, optionally complexed with liposomes, to cardiac tissue of a subject.

70. The method of claim 69 wherein the subject suffers from a heart disease.